UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT DAYTON

JOY REYNOLDS,	:	
	:	
Plaintiff,	:	Case No. 3:20-cv-403
	:	
v.	:	Judge Thomas M. Rose
	:	
MEDTRONIC, INC., *et al.*,	:	
	:	
Defendants.	:	

ENTRY AND ORDER GRANTING, IN PART, AND DENYING, IN PART, DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT (ECF NO. 13)

This is a products liability case brought by Plaintiff Joy Reynolds ("Reynolds").[1] In her First Amended Complaint (the "Complaint"), Reynolds brings state-law claims under Ohio law against Medtronic based on her use of an allegedly defective Medtronic SynchroMed II pump system. (*See* ECF No. 12.) In the Motion to Dismiss (ECF No. 13) (the "Motion"), Medtronic argues that Reynolds's claims are expressly preempted by federal law, impliedly preempted, or inadequately pleaded and deficient under Ohio law. (ECF No. 13.) Therefore, Medtronic moves the Court to dismiss the Complaint for failure to state a claim upon which relief may be granted, pursuant to Federal Rule of Civil Procedure 12(b)(6). In response, Reynolds argues that her claims are parallel claims that escape preemption and comply with the pleading standards. (ECF No. 14.) For the reasons discussed below, the Court **GRANTS** the Motion with respect to Counts 2 and 3 in the Complaint, but **DENIES** the Motion with respect to Counts 1 and 4.[2]

[1] The Defendants in this lawsuit are Medtronic, Inc.; Medtronic USA, Inc.; Medtronic Logistics, LLC; and Medtronic Puerto Rico Operations Co. (collectively, "Medtronic"). They are alleged to be related companies (ECF No. 12 at PageID 272-73), and they jointly filed the motion at issue in this order.
[2] Medtronic requests oral argument on the Motion, but the Court denies that request. S.D. Ohio Civ. R. 7.1.

I. BACKGROUND

This background section is based on allegations made by Reynolds in the Complaint. According to the Complaint, "Reynolds suffered severe injuries and hospitalizations as a foreseeable, direct, and proximate result of the defects in the Medtronic SynchroMed II Programmable Implantable Infusion Pump System for intrathecal drug delivery, which was implanted in her abdomen." (ECF No. 12 at PageID 271.)

The SynchroMed II Programmable Implantable Infusion Pump System (the "Device") is a Class III medical device. (*Id.* at PageID 278.) It is a programmable drug infusion system implanted in the body for drug delivery. (*Id.* at PageID 277.) The Device includes an infusion pump connected to a thin, flexible catheter attached to a patient's intrathecal space (spinal canal), into which the pump delivers medication. (*Id.*) Each of the Defendants is involved in the Device's design, assembly, manufacture, testing, packaging, labeling, marketing, distribution, sale, and/or promotion. (*Id.* at PageID 273)

The U.S. Food and Drug Administration ("FDA") approved the Device through the Premarket Approval ("PMA") process on March 14, 1988. (*Id.* at PageID 278.) Since its initial approval, Medtronic has sought FDA approval of numerous supplements or changes to the Device originally approved. (*Id.*; *see also* ECF No. 13 at PageID 534-35 and its Exhibits A, B, and C (indicating approval of various supplements).)

Medtronic (allegedly) knew there was a manufacturing problem with the catheters used in the Device and that there have been such problems for years. (ECF No. 12 at PageID 280.) Internal Medtronic documents dating back nearly a decade (allegedly) establish both that the catheters were always problematic and that Medtronic knew the catheters were problematic. (*Id.*) Medtronic included summaries of these problems in each of its Product Performance Reports, including

reports from 2012 through 2018. (*Id.* at PageID 280-84.) The FDA has issued at least 19 recalls concerning SynchroMed II pump models and at least 27 recalls concerning SynchroMed II catheters and catheter-pump connectors during the time the Device has been on the market. (*Id.* at PageID 299-303.) On September 21, 2017, Medtronic initiated a recall of the Medtronic Ascenda Intrathecal Catheter for the SynchroMed II pump (the "Z-0537-2018 recall"). (*Id.* at PageID 308.) The FDA posted the Z-0537-2018 recall on February 6, 2018, and the recall was terminated on March 20, 2020. (*Id.*) The recall was issued because of the possibility that some distributed catheters were at risk for an increased potential for kinking at the proximal end where the catheter connects to the drug infusion pump. (*Id.*)

Moreover, in 2006, 2007, 2008, 2009, 2012, and 2013, the FDA conducted numerous inspections of Medtronic's manufacturing and quality-control facilities in Minnesota and Puerto Rico, (allegedly) discovering many significant violations of federal law governing the manufacture and quality control of PMA medical devices, including the Device and associated intrathecal catheters, as recorded in FDA Form 483s and Warning Letters issued to Medtronic. (*Id.* at PageID 289-98.) This includes that the methods used in, or the facilities or controls used for, their manufacture, packaging, storage, or installation were not in conformance with the Good Manufacturing Practices ("GMPs") issued by the FDA. (*Id.* at PageID 289-90.) In fact, throughout the Device's history, the FDA has repeatedly notified Medtronic that the Device's manufacturing failed to conform to manufacturing requirements enumerated in federal regulations and statutes. (*Id.* at PageID 298.) Reynolds alleges that those federal violations caused defects and malfunctions in her Device, resulting in her injuries and damages. (*Id.*)

Reynolds has an extensive pain history and a past medical history of Degenerative Disc Disease, among other ailments. (*Id.* at PageID 274.) On or about September 6, 2018, after

consultation regarding her chronic pain, Reynolds had a Device implanted in her body to deliver pain medication. (*Id.*) This took place during the time of the Z-0537-2018 recall. (*Id.* at PageID 308.) In addition to the Device's failure to reduce her pain, Reynolds experienced new pain at the site of the Device in the weeks afterward. (*Id.* at PageID 274.) On or about September 29, 2018, physicians told Reynolds that MRIs showed the implanted catheter was wrapped around a bulging disc in her back. (*Id.* at PageID 275.) On October 29, 2018, while continuing to suffer from severe pain, Reynolds's physicians determined that the implanted Device "was free and able to rotate/twist, and that every time the Device was twisting it would cause a kink in the catheter." (*Id.* at PageID 276.) A physician recommended that she have the Device "revised." (*Id.*)

On or about January 15, 2019, a doctor removed Reynolds's Device from her body. (*Id.*) The doctor noted in an operative report that there was severe twisting of the catheter throughout the flank, possibly being the reason for its kinking off. (*Id.*) The doctor also noted that it was difficult to ascertain whether the actual catheter had sheared off from the Device insertion site or from the Device itself right at the connector. (*Id.*) Additionally, it was found that the sutures from the previous anchoring of the Device were loose and the pump was free in the pocket. (*Id.*) Reynolds experienced a significant reduction in her pain levels after the Device was removed. (*Id.* at PageID 277.)

Reynolds alleges that, due to its defects and malfunctions, her Device failed to deliver the prescribed medications as programmed, resulting in underdosing and withdrawal from opiate and benzos medications, as well as severe pain and the inability to properly manage her pain. (*Id.*) More specifically, she experienced a lack of therapeutic effect because the medication from the pump was not delivered into her intrathecal spine space due to the catheter kinking or shearing off from the Device insertion site or from the Device itself at the connector. (*Id.* at PageID 308-09.)

This caused her to incur additional medical bills and suffer pain, lasting injury, mental anxiety, and depression. (*Id.* at PageID 277.)

The Complaint brings four claims against Medtronic, all under Ohio law: (1) Strict Liability Manufacturing Defect (Ohio Rev. Code § 2307.74); (2) Strict Liability Inadequate Warning or Instruction (Ohio Rev. Code § 2307.76); (3) Breach of Implied Warranty of Merchantability (Ohio Rev. Code §§ 1302.27 & 1302.28); and (4) Punitive Damages (Ohio Rev. Code § 2315.21(C)(1)). The Complaint alleges that this Court has diversity subject-matter jurisdiction over the action pursuant to 28 U.S.C. § 1332(a). (ECF No. 12 at PageID 274.)

On February 18, 2021, Medtronic filed the Motion, seeking dismissal of the Complaint. (ECF No. 13.) On March 3, 2021, Reynolds filed her Response to the Motion (ECF No. 14) (the "Response"). And, on March 17, 2021, Medtronic filed a Reply memorandum in support of the Motion (ECF No. 15) (the "Reply"). The Motion is fully briefed and ripe for review and decision.

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint contain a "short and plain statement of the claim showing that the pleader is entitled to relief." While this rule "does not require 'detailed factual allegations' … it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)).

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the sufficiency of the complaint. Fed. R. Civ. P. 12(b)(6) (providing for motions to assert a "failure to state a claim upon which relief can be granted"). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678. A claim is facially plausible when it includes "factual content

that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* This standard is not the same as a probability standard, but "asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (internal quotation marks omitted). Thus, if a plaintiff has "not nudged [its] claims across the line from conceivable to plausible, [the] complaint must be dismissed." *Twombly*, 550 U.S. at 570.

When ruling on a motion to dismiss, the Court must accept the factual allegations of the complaint as true and construe them in a light most favorable to the non-moving party. *Twombly*, 550 U.S. at 554-55. However, the Court is not bound to accept as true a legal conclusion couched as a factual allegation. *Id.* at 555-56. "In evaluating a motion to dismiss [a court] may consider the complaint and any exhibits attached thereto, public records, items appearing in the record of the case and exhibits attached to the defendant's motion to dismiss so long as they are referred to in the complaint and are central to the claims contained therein." *Luis v. Zang*, 833 F.3d 619, 626 (6th Cir. 2016) (internal quotation marks omitted).

III. ANALYSIS

Medtronic asks the Court to dismiss all claims in the Complaint, pursuant to Federal Rule of Civil Procedure 12(b)(6). Medtronic argues that Reynolds's claims do not "plead facts establishing a 'parallel' claim," which it says is the only type of claim that can avoid preemption in "[c]laims involving Class III prescription medical devices with" PMA. (ECF No. 13 at PageID 532.) Medtronic also argues that the claims should be dismissed pursuant to Federal Rules of Civil Procedure 8(a) and 12(b)(6) because they allegedly are "insufficiently pled and deficient under Ohio law." (*Id.*)

In response, Reynolds argues that "[t]here is a strong presumption against preemption and

federal law does not preempt state causes of action that arise out of violations of federal law." (ECF No. 14 at PageID 599.) She asserts that the Complaint adequately pleads "parallel claims," so therefore her claims "are not expressly or impliedly preempted." (*Id.*)

A. Judicial Notice of Certain Documents

The Court first addresses a preliminary issue: whether to take judicial notice of certain documents attached to the Motion. Medtronic asks the Court to take judicial notice of the "approval listings attached [to the Motion that] are accessible via the FDA's searchable database." (ECF No. 13 at PageID 534.) In support, Medtronic explains that the documents are government records and cites to other cases where "courts have taken judicial notice of the PMA status of the SynchroMed® II System based on the FDA website." (*Id.* at PageID 534-35.) Reynolds does not oppose (or even address) this request in her Response.

"In ruling on a motion to dismiss, the Court 'may consider materials in addition to the complaint if such materials are public records or are otherwise appropriate for the taking of judicial notice.'" *Mories v. Boston Sci. Corp.*, 494 F. Supp. 3d 461, 469 (S.D. Ohio 2020) (quoting *New England Health Care Emps. Pension Fund v. Ernst & Young, LLP*, 336 F.3d 495, 501 (6th Cir. 2003)). Doing so does not convert a motion to dismiss into a motion for summary judgment. *Id.*; *Goryoka v. Quicken Loan, Inc.*, 519 F. App'x 926, 927 (6th Cir. 2013) ("[m]atters of public record may be considered on a motion to dismiss").

Here, the Court will take judicial notice of the approval listings, which are public records available from the FDA's government database website. Fed. R. Evid. 201(b) (a court may judicially notice a fact that is not subject to reasonable dispute because it can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned); *City of Monroe Emps. Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 655 n.1 (6th Cir. 2005) (taking judicial notice of information posted on a website); *Mories*, 494 F. Supp. 3d at 469 (granting defendants'

request to take judicial notice of public documents, including those filed with the FDA); *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1014 (S.D. Ohio 2016) (taking judicial notice of manufacturer's receipt of PMA from the FDA, including the device's FDA-mandated warning label).

B. Medical Device Amendments to the Federal Food, Drug and Cosmetics Act

1) Regulation of Class III medical devices

In 1976, Congress enacted the Medical Device Amendments ("MDA") "to provide for the safety and effectiveness of medical devices intended for human use." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) ("*Lohr*") (internal quotation marks omitted). The MDA modified the Federal Food, Drug and Cosmetics Act ("FDCA"). The MDA "swept back some state obligations and imposed a regime of detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008). "The new regulatory regime established various levels of oversight for medical devices, depending on the risk they present." *Id.* Medical "devices receiving the most federal oversight are those in Class III." *Id.* at 317. "In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)). For example, the pacemaker at issue in *Riegel* was a Class III medical device.

"Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a 'reasonable assurance' that the device is both safe and effective." *Lohr*, 518 U.S. at 477 (citing 21 U.S.C. § 360e(d)(2)). "[T]he process of establishing this 'reasonable assurance,' which is known as the 'premarket approval,' or 'PMA' process, is a rigorous one."

Id.; *see also Riegel*, 552 U.S. at 317 (the MDA "established a rigorous regime of premarket approval for new Class III devices"). The PMA process "includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a 'full statement' of the device's 'components, ingredients, and properties and of the principle or principles of operation'; 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device'; samples or device components required by the FDA; and a specimen of the proposed labeling." *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360e(c)(1)). The PMA process also "includes review of the device's proposed labeling." *Id.* "The FDA evaluates safety and effectiveness under the conditions of use set forth on the label and must determine that the proposed labeling is neither false nor misleading." *Id.* (internal citation omitted).

In determining whether to grant PMA, the FDA "must 'weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)) (modifications adopted). Therefore, the FDA may "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id.* However, as referenced above, the FDA grants PMA "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* (quoting 21 U.S.C. § 360e(d)).

Once a device has received PMA, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319; *see also* 21 U.S.C. § 360e(d)(5). "If the applicant wishes to make such a change, it must submit, and the FDA must

approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." *Id.*

Devices that have received PMA are also "subject to reporting requirements." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360i)). "These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonable should know of … and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." *Id.*; *see also* 21 C.F.R. §§ 803.50(a), 814.84(b)(2). "The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw premarket approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Riegel*, 552 U.S. at 319-20; *see also* 21 U.S.C. §§ 360e(e)(1), 360h(e).

Additionally, device manufacturers are required to comply with Good Manufacturing Practices (again, "GMPs"). *Lohr*, 518 U.S. at 497. "The GMPs are FDA regulations based upon manufacturing standards that apply to all FDA-regulated medical devices." *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 439 (6th Cir. 2010); *see generally* 21 C.F.R. Part 820.

2) Preemption under the Medical Device Amendments

"Congress intended that the MDA be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001) (citing 21 U.S.C. § 337(a)). The Supreme Court in *Buckman* explained that "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" *Id.* at 349 n.4 (quoting 21 U.S.C. § 337(a)). Therefore, a plaintiff cannot bring a claim

that only alleges a violation of the MDA. 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 352. Additionally, state-law claims that allege fraud-on-the-FDA "conflict with, and are therefore impliedly pre-empted by, federal law." *Id.* at 348; *see also id.* at 350 ("[s]tate-law fraud-on-the FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives"). For example, in *Buckman*, the plaintiffs' claims that the defendant "made fraudulent representations to the [FDA] in the course of obtaining approval to market" the device at issue were preempted. *Id.* at 343-44. The plaintiffs in that case had alleged that, if the representations had not been made, then the FDA would not have approved the device and, therefore, plaintiffs would not have been injured by it. *Id.*

The MDA also includes an express preemption provision, which the Supreme Court has explained preempts most, but not all, common law tort claims under state law involving FDA-regulated medical devices. *See Riegel*, 552 U.S. at 321-22, 330; *Howard*, 382 F. App'x at 439 ("[t]he Supreme Court has interpreted § 360k(a) to preempt most common-law tort duties"). The preemption provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).[3] The Supreme Court explained that the text of the statute "suggests that the solicitude for those injured by FDA-approved devices … was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to

[3] Although not applicable here, subsection (b) of the statute provides an exception that "permits the FDA to exempt some state and local requirements from pre-emption." *Riegel*, 552 U.S. at 316; *see* 21 U.S.C. § 360k(b).

apply the tort law of 50 States to all innovations." *Riegel*, 552 U.S. at 326. However, the text also demonstrates that "the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable … to the device' under federal law." *Riegel*, 552 U.S. at 321 (quoting 21 U.S.C. § 360k(a)(1)). The preemption provision's "[r]eference to a State's 'requirements' includes its common-law duties, including, for example, common-law causes of action for negligence and strict liability." *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901, 905 (S.D. Ohio 2012) (internal quotation marks omitted) (citing *Riegel* and *Lohr*).

Based on the statutory language, the Supreme Court in *Riegel* adopted a two-part test for determining whether the MDA expressly preempts a state-law claim. First, the court "must determine whether the Federal Government has established requirements applicable to" the medical device at issue. *Riegel*, 552 U.S. at 321. Second, if so, the court "must then determine whether the [plaintiff's] common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* (quoting 21 U.S.C. § 360k(a)). "[A]ny state-law requirement imposed on an FDA-regulated medical device that is 'different from, or in addition to,' FDA requirements is preempted." *Mories*, 494 F. Supp. 3d at 468 ("the MDA does not permit a state to impose different or additional regulations on Class III medical devices").

Applying the *Riegel* test involves determining whether a claim qualifies as a "parallel claim." More specifically, the preemption statute "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (citing *Lohr*, 518 U.S. at 495). The Supreme Court explained that "[t]he presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the [preemption] statute;

rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Lohr*, 518 U.S. at 495. Thus, there is a "narrow gap" in the preemption statute that "allows state law claims premised on a violation of FDA regulations to avoid express preemption." *Warstler v. Medtronic, Inc.*, 238 F. Supp. 3d 978, 985 (N.D. Ohio 2017).

"Parallel claims must be specifically stated in the initial pleadings." *Wolicki-Gables v. Aarow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011). "To state a parallel claim and avoid preemption under § 360k(a), a plaintiff must identify state law that parallels" a federal regulation or federal requirement that applies to the medical device at issue. *Mories*, 494 F. Supp. 3d at 471. The plaintiff must also allege that the defendant violated that federal regulation or federal requirement. *Id.*; *Wolicki-Gables*, 634 F.3d at 1301; *see also Riegel*, 552 U.S. at 330 (explaining that the district court decided plaintiff's claims were preempted because those claims asserted that the device violated state tort law notwithstanding compliance with the relevant federal requirements). And, the plaintiff must set forth factual allegations regarding "how the medical device at issue violated the federal regulation" or federal requirement and link the alleged violation to plaintiff's alleged injury. *Mories*, 494 F. Supp. 3d at 471; *see also Wolicki-Gables*, 634 F.3d at 1301-02 ("[t]o properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated," but the allegations in the complaint did not "set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged") (internal quotation marks omitted).

C. Applying the *Riegel* Test's First Step

Applying the first step of the *Riegel* test to Reynolds's claims, the Court finds that the Federal Government has established requirements applicable to the Device. *Riegel*, 552 U.S. at 321. The Device is subject to federal requirements because it received PMA from the FDA.

Warstler, 238 F. Supp. 3d at 986 ("[t]he device at issue understandably meets the first inquiry: the PMA provides the framework for regulating the SynchroMed II as a Class III medical device," and "[t]he Court in *Riegel* specifically held that premarket approval…imposes [federal] requirements as that term is used in § 360k(a)") (internal quotation marks omitted); *Mories*, 494 F. Supp. 3d at 468 ("[a]ll PMA-approved medical devices, including Class III medical devices, automatically fulfill this first step"). Reynolds does not even attempt to argue otherwise. (*See* ECF No. 14.) Therefore, the Court proceeds to the second step of the *Riegel* test.

D. Applying the *Riegel* Test's Second Step

The second step of the *Riegel* test involves considerably more analysis. As an initial matter, "[s]afety and effectiveness are the very subjects of [Reynolds's] common-law claims, so the critical issue is whether [Ohio's] tort duties constitute 'requirements' under the MDA." *Riegel*, 552 U.S. at 323; *see also Warstler*, 238 F. Supp. 3d at 986 n.4 (plaintiff's Ohio state-law claims for manufacturing defect, failure to warn, and breach of implied warranty "clearly relate to the 'safety and effectiveness' of SynchroMed II"). The Court will analyze the remainder of the test's second step separately for each of Reynolds's three substantive claims, as well as (if necessary) consider whether any are impliedly preempted in accordance with *Buckman* and whether Reynolds's pleading is sufficient.

1) Strict liability manufacturing defect claim (Count 1)

Count 1 is a claim under Ohio law for strict liability due to manufacturing defect, pursuant to Ohio Rev. Code § 2307.74.[4] The elements for such a claim are found at Ohio Rev. Code § 2307.73. For a manufacturer to be found liable for a manufacturing defect, the plaintiff must

[4] That statute states: "A product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction." Ohio Rev. Code § 2307.74.

establish that: (1) the manufacturer's product in question was defective in its manufacture or construction, as described in Ohio Rev. Code § 2307.74; (2) a defective aspect of that product was a proximate cause of harm for which the plaintiff seeks damages; and (3) the manufacturer designed, produced, constructed, assembled, or rebuilt the actual product that caused the harm. Ohio Rev. Code § 2307.73(A)(1)-(3); *see also* Ohio Rev. Code § 2307.71 (providing applicable definitions); Ohio Rev. Code § 2307.74.

Reynolds alleges that the particular Device implanted in her body was manufactured in deviation from the Device's manufacturing specifications, in violation of federal requirements and Ohio law that parallels those federal requirements. (ECF No. 12 at PageID 309.) Among other allegations, the Complaint also specifically alleges that Ohio Rev. Code § 3715.52 parallels particular federal law applicable to the Device: 21 U.S.C. §§ 331(a)-(c) and (k). (ECF No. 12 at PageID 312.) As a general matter, that Ohio statute prohibits the manufacture, sale, or delivery of any device that is adulterated or misbranded; adulterating or misbranding any device; and delivering for pay any device that is adulterated or misbranded. Ohio Rev. Code §§ 3715.52(A)(1), (2), and (3). And, as a general matter, 21 U.S.C. §§ 331(a)-(c) and (k) prohibit a manufacturer from introducing, selling, or delivering an adulterated device.[5]

The Complaint also alleges that the Device implanted in Reynolds's body violated federal law. More specifically, she alleges that—due to Medtronic's violations of regulations within 21 C.F.R. Part 820 (GMPs)—her device was adulterated and misbranded, was received in interstate commerce, and was delivered for pay while adulterated, in violation of 21 U.S.C. §§ 331(c) and

[5] 21 U.S.C. § 331 provides, in part, that "[t]he following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce of any…device…that is adulterated or misbranded [and] … (c) The receipt in interstate commerce of any…device…that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise [and] … (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a…device…if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded." 21 U.S.C. §§ 331(a), (c), (k).

(k), as well as Ohio Rev. Code §§ 3715.52(A)(1), (2), and (3).[6] (ECF No. 12 at PageID 313.) She alleges that the Device implanted in her body was defectively manufactured, having deviated from the Device's design, formula, and/or performance standards established by federal regulations and requirements. (*Id.* at PageID 309, 311, 313.) Among other allegations, Reynolds states that her medical records indicate that the catheter of the Device implanted in her body was manufactured and sold in a physically defective state, resulting in it shearing off from the Device's (pump) insertion site or from the Device itself at the connector. (*Id.* at PageID 311, 313.) According to Reynolds, this caused the catheter to be loose in her body, severely twisting and ultimately kinking off, thus prohibiting the delivery of medication for pain management—the specified function of a Device. (*Id.*)

The Complaint further alleges that, therefore—and as a foreseeable, direct, and proximate result—the Device implanted in her body "failed to deliver the prescribed medication as programmed, resulting in overdosing/underdosing and withdrawal from opiate medications as well as severe pain and failure to properly manage her pain." (ECF No. 12 at PageID 313.) The alleged manufacturing defects in her particular Device caused Reynolds to suffer through "several unnecessary medical procedures," "MRIs with and without contrast, multiple visits to medical facilities, and another surgery to remove the violative Device." (*Id.*)

The Court finds that Count 1 adequately pleads a plausible parallel claim for relief and avoids preemption. Based on the allegations in the Complaint, it does not appear that Count 1 is "based upon [state] requirements with respect to the device that are 'different from, or in addition

[6] Within 21 C.F.R. Part 820, 21 C.F.R. 820.1(c) states that "[t]he failure to comply with any applicable provision in this part [i.e., 21 C.F.R. 820] renders a device adulterated under" 21 U.S.C. § 351(h). 21 U.S.C. § 351 discusses when a medical device is adulterated, and its subsection (h) states that a "device shall be deemed to be adulterated—[i]f it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 360j(f)(1) of [Title 21] or an applicable condition prescribed by an order under section 360j(f)(2) of" Title 21. 21 U.S.C. § 351(h).

to,' the federal ones." *Riegel*, 552 U.S. at 321 (quoting 21 U.S.C. § 360k(a)). Additionally, the Complaint makes factual allegations that plausibly indicate Medtronic deviated from federal requirements when it manufactured the Device implanted in Reynolds's body. (*See, e.g.*, ECF No. 12 at PageID 274-76, 309-310, 311-12, 313.)

The Court agrees with Reynolds that Count 1 sufficiently states a parallel claim. *See Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 495; *Wolicki-Gables*, 634 F.3d at 1301-02; *Mories*, 494 F. Supp. 3d at 471-72 (denying motion to dismiss plaintiff's Ohio state-law strict liability manufacturing defects claim where the complaint alleged that the defendant's "manufacture of the [device] failed to comply with PMA specifications and was generally non-conforming" and the claim was "predicated on a failure to meet the FDA's requirements"). First, the Complaint's allegations identify state law that parallels federal requirements applicable to the medical device at issue. (*See, e.g.*, ECF No. 12 at PageID 312.) Second, it alleges that Medtronic violated those federal requirements with respect to the Device implanted in her body. (*See, e.g., id.* at PageID 313.) Third, it sets forth factual allegations regarding how the Device implanted in her body deviated from the manufacturing specifications in 21 C.F.R. Part 820 and violated the federal requirements. (*See, e.g., id.* at PageID 271, 274-76, 309-12, 313.) And, it links the alleged violation to Reynolds's alleged injuries.[7] (*See, e.g., id.* at PageID 277, 313.) Therefore, as in *Mories*, "to the extent—and only to the extent—[Reynolds's] claim that the device was defectively … manufactured because it did not comply with the FDA-approved specifications, this Court finds that [Reynolds] has successfully alleged a parallel claim sufficient to survive preemption under" 21 U.S.C. § 360k. *Mories*, 494 F. Supp. 3d at 471-72.

[7] This contrasts with, for example, the plaintiffs' claim in *Anderson*, where the court found that the complaint did not plead a parallel claim because, "[i]n essence, the complaint alleges that Defendant [manufacturer] violated state law notwithstanding its compliance with the FDA premarket approval process." *Anderson v. Boston Sci. Corp.*, No. 1:12-cv-00762, 2013 U.S. Dist. LEXIS 22982, 2013 WL 632379, at *4 (S.D. Ohio Feb. 20, 2013).

Additionally, Count 1 is not impliedly preempted by federal law. The count does not allege fraud-on-the-FDA and is not a claim to enforce the MDA or other federal requirements.[8] *Buckman*, 531 U.S. at 349. It is a strict liability claim concerning an alleged manufacturing defect brought pursuant to Ohio law. And, Reynolds sufficiently states a cause of action under Ohio law for strict liability due to manufacturing defect that is plausible on its face (*see, e.g.*, ECF No. 12 at PageID 271, 273, 274-77, 309, 311-12, 313). *Iqbal*, 556 U.S. at 678; *see also* Ohio Rev. Code §§ 2307.73, 2307.74. Therefore, Count 1 survives dismissal at this stage.[9] Of course, this does not mean that Reynolds has actually proven that the claim is not preempted. *See, e.g.*, *Carter v. Medtronic, Inc.*, No. 2:18-cv-724, 2020 U.S. Dist. LEXIS 82374, 2020 WL 2319729, at *6 (S.D. Ohio May 11, 2020) (granting summary judgment for defendants on state law manufacturing defect claim because the plaintiff "failed to establish a genuine dispute of material fact that Defendants violated an FDA requirement, and her claims are therefore preempted by the MDA").

2) Strict liability inadequate warning or instruction claim (Count 2)

Count 2 is a claim under Ohio law for strict liability due to inadequate warning or instruction. Reynolds alleges that Medtronic improperly "concealed material facts regarding risks associated with SynchroMed II Devices and catheters including those which caused Ms. Reynolds'

[8] Medtronic's reliance on *Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012) to argue for implied preemption is off-the-mark, at least for purposes of Count 1. (*See* ECF No. 13 at PageID 549-50.) The claim at issue in *Marsh* involved an alleged "failure to submit reports to the FDA," which the Sixth Circuit explained "is arguably a species of fraud on the [FDA] under" the Michigan Products Liability Act. *Marsh*, 693 F.3d at 553. The Sixth Circuit's decision that the claim fell within the concerns expressed by *Buckman* was not simply because the claim relied on an alleged violation of a federal regulation, but because it involved a type of state-law claim that alleges fraud-on-the-FDA—an alleged wrong "perpetrated upon the agency, [which] thus implicates the 'inherently federal' relationship described in *Buckman*." *Id.*; *see also Riegel*, 552 U.S. at 330 (the preemption statute at § 360k(a) "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements"). The Court disagrees with Medtronic's broad assertion at ECF No. 13 at PageID 549 that *Marsh* found "that a private tort claim predicated on an alleged violation of an FDCA regulation is impliedly preempted by 21 U.S.C. § 337(a) as interpreted in *Buckman*." *Id.*

[9] The Court clarifies that its determination does not rely on the Complaint's many paragraphs that describe FDA inspections, FDA warning letters, FDA-issued recalls, or Product Performance Reports from years before Reynolds had her Device implanted in her body.

injuries and damages." (ECF No. 12 at PageID 314.) According to Reynolds, "[a] manufacturer exercising reasonable care would have provided consumers with information concerning the risks associated with SynchroMed II catheters, specifically the intrathecal catheters' increased potential for kinking where the catheter connects to the pump, the subject of a Class III recall." (*Id.*) Among other allegations, Reynolds asserts that, despite Medtronic's various representations, the Device implanted in her was misbranded and was defective as sold, leading to her injuries. (*Id.* at PageID 314-17.)

The Court finds that Count 2 must be dismissed because it fails to adequately state a claim that shows Reynolds is entitled to relief. It fails to state a parallel claim because, in the context of this inadequate warning claim, Reynolds's allegations do not meet the requirement that she "identify state law that parallels federal regulations" or requirements that Medtronic allegedly violated.[10] *Mories*, 494 F. Supp. 3d at 471; *see also Aaron*, 209 F. Supp. 3d at 1005 ("the federal duty to report certain information to the FDA is not identical, and thus not parallel, to the state-law duty to provide warnings to patients or their physicians") (emphasis, internal citation, and internal quotation marks omitted). Additionally, allegations indicate that this claim is based on state requirements that are "different from, or in addition to" the federal requirements applicable to the device. 21 U.S.C. § 360k(a); *Aaron*, 209 F. Supp. 3d at 1005 ("to the extent that Plaintiffs allege that Defendants were required to give any warning other than those that were required by the FDA as part of its PMA of [the device], those claims are expressly denied as being inconsistent with federal law"); *Riegel*, 552 U.S. at 329 (the preemption provision surely "would pre-empt a jury determination that the FDA-approved labeling for a [device] violated a state common-law

[10] Reynolds relies on *Grubbs v. Smith & Nephew, Inc.*, No. 1:19-cv-248, 2020 U.S. Dist. LEXIS 162317, 2020 WL 5305542 (S.D. Ohio Sept. 4, 2020) to defend Count 2, but *Grubbs* did not involve preemption under the MDA or parallel claims.

requirement for additional warnings"). For example, paragraph 134 alleges that "Medtronic failed to provide additional warning or instruction equal to the seriousness of the harm under which this claim is brought." (ECF No. 12 at PageID 316; *see also id.* at PageID 318 ("Plaintiff claims that her particular SynchoMed II device was defective for failure to provide adequate warnings because her individual device was defective.").) As pleaded in the Complaint, the claim is preempted because it does not fall within the "narrow gap" for avoiding express preemption in accordance with *Riegel*'s two-part test.[11]

Finally, Renyolds says that the Motion "should be dismissed to allow [her] time to conduct discovery." (ECF No. 14 at PageID 616.) However, a plaintiff's "claims must meet the pleading standards of Rule 8 as defined in *Iqbal* and *Twombly* in order to survive a motion to dismiss." *Aaron*, 209 F. Supp. 3d at 1001; *see also Becker v. Smith & Nephew, Inc.*, Civ. No. 15-2538, 2015 U.S. Dist. LEXIS 102385, 2015 WL 4647982, at *3 (D.N.J. Aug. 5, 2015) ("[p]laintiffs contend that they should be permitted to allege unspecified deviations from FDA requirements at the pleading stage, and fill in the blanks through discovery … [b]ut a plaintiff must successfully plead a claim before obtaining discovery, not the other way around"). In the context of medical device claims, courts have found that, based on the plaintiff's own medical records and access to the FDA's website, the "plaintiff could have, with reasonable effort, described the federal requirements that have allegedly been violated and any parallel state statute." *Warstler*, 238 F. Supp. 3d at 985 n.3 (internal quotation marks omitted). Court 2 is dismissed.

3) Breach of implied warranty of merchantability claim (Count 3)

Count 3 suffers from the same failure as Count 2. The Court finds that it too must be

[11] Given this outcome, the Court does not decide whether the claim would also be impliedly preempted in accordance with *Buckman*. *See Warstler*, 238 F. Supp. 3d at 991-92 ("Because I already concluded that the FDCA expressly preempts plaintiff's claims, I decline to address whether the Act impliedly preempts his claims as well").

dismissed because it fails to adequately state a claim that shows Reynolds is entitled to relief. It fails to state a parallel claim because, in the context of the implied warranty of merchantability claim, Reynolds's allegations do not meet the requirement that she "identify state law that parallels federal regulations" or requirements that Medtronic allegedly violated. *Mories*, 494 F. Supp. 3d at 471. In fact, the allegations tend to demonstrate that the cited state requirements are "different from, or in addition to" the federal requirements applicable to the device and, therefore, are preempted. 21 U.S.C. § 360k(a). This is not particularly surprising given that, "[w]hen plaintiffs have brought these types of [breach of implied warranty] claims, courts have consistently found that state law claims for breach of warranties on the safety or effectiveness of a PMA device[] impose requirements that are different from, or in addition to[,] federal regulations, and thus are preempted." *Warstler*, 238 F. Supp. 3d at 990 (internal quotation marks omitted) (alteration adopted). As pleaded in the Complaint, the claim is preempted because it does not fall within the "narrow gap" for avoiding express preemption in accordance with *Riegel*'s two-part test.[12] And, as with Count 2, to the extent that Reynolds argues that the Motion should be dismissed to allow her time to conduct discovery, the Court disagrees. Count 3 is dismissed.

E. Punitive Damages Claim (Count 4)

Count 4, Reynolds's claim for punitive damages, is a derivative claim whose survival relies on the survival of at least one of her three primary claims. *See Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514-15 (6th Cir. 2003) (a claim for punitive damages is "derivative in nature" and "[a] derivative cause of action may not provide greater relief than that available under the primary cause of action," so a derivative punitive damages claim must be dismissed when all primary causes of action have been dismissed); *Stolz v. J & B Steel Erectors, Inc.*, 76 F. Supp. 2d 696, 703

[12] As with Count 2, given this outcome, the Court does not decide whether the claim would also be impliedly preempted in accordance with *Buckman*.

(S.D. Ohio 2014) (Ohio punitive damages claim is a derivative action that must be dismissed when the primary claim does not survive).

Medtronic argues that Reynolds's punitive damage claim should be dismissed for a "lack of adequate facts alleged in the" Complaint. (ECF No. 13 at PageID 551.) The Court disagrees and believes that the facts alleged in the Complaint—which, again, must be accepted as true and construed in a light most favorable to Reynolds for purposes of the Motion–are sufficient to meet pleading standards. *Twombly*, 550 U.S. at 554-55; *see also Marcum v. Depuy Orthopedics, Inc.*, No. 1:12-cv-834, 2013 U.S. Dist. LEXIS 62875, 2013 WL 1867010, at *6-7 (S.D. Ohio May 2, 2013) (allegations sufficiently stated a claim for punitive damages in a case claiming that a medical device was adulterated); *Frederick v. Smith & Nephew, Inc.*, No. 1:13-cv-1220, 2013 U.S. Dist. LEXIS 170938, 2013 WL 6275644, at *4 (N.D. Ohio Dec. 4, 2013) ("[t]he nature of the conduct in question that plaintiff alleges supports a punitive damages claim is sufficiently detailed throughout the complaint to put defendant on notice of a plausible claim and withstand defendant's motion to dismiss" the claim for punitive damages). However, this obviously does not mean that Reynolds will necessarily be entitled to punitive damages even if she succeeds on her sole surviving primary cause of action: her strict liability due to manufacturing defect claim (Count 1). *See* Ohio Rev. Code § 2307.80 (requirements for awarding punitive damages); Ohio Rev. Code § 2307.72 (any recovery of punitive damages in connection with a product liability claim is subject to portions of the Ohio Product Liability Act); *see also* Ohio Rev. Code § 2315.21 (requirements for recovery of compensatory, punitive, or exemplary damages in a tort action).

IV. CONCLUSION

For the reasons stated above, the Court **GRANTS, IN PART, AND DENIES, IN PART,** Defendants' Motion (ECF No. 13). Counts 2 and 3 of the Complaint are insufficiently pleaded to

be parallel claims allowed by the MDA. Therefore, those two claims are preempted and dismissed. In contrast, Count 1 is adequately pleaded as a plausible parallel claim that avoids preemption at this stage. The case will proceed on Counts 1 and 4 of the Complaint, but Count 1 will be limited in accordance with this Order.

DONE and **ORDERED** in Dayton, Ohio, this Monday, May 10, 2021.

s/Thomas M. Rose

THOMAS M. ROSE
UNITED STATES DISTRICT JUDGE